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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/766,783

01/27/2004

A. Satyanarayan Naidu

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09/25/2006

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EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/766,783	Applicant(s) NAIDU, A. SATYANARAYAN	
	Examiner Lezah W. Roberts	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 26-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>27 Jan 2004</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election of Species

This application contains claims directed to the following patentably distinct species: a filament material such as a dental floss and a suture.

The species are independent or distinct because a suture is used to apply stitches and may be used in the oral cavity or other parts of the body, whereas dental floss primarily used to clean between the teeth. A search for a suture will not necessarily yield results for dental floss.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

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During a telephone conversation with Jeffrey Craft on August 10, 2006 a provisional election was made with traverse to prosecute the invention of a dental floss, claims 1-25. Affirmation of this election must be made by applicant in replying to this Office action. Claims 26-37 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species.

Claims

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 1 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Galley et al. (US 5,607,681).

Galley et al. teach antimicrobial compositions. The compositions may comprise additional antimicrobial agents such as lactoferrin (col. 3, lines 29-33). The compositions may be used to impregnate dental floss (col. 6, lines 3-4), also a filament as recited in claim 1. The reference anticipates the instant claims insofar as it teaches filament compositions having a surface for reducing microbial contamination comprising lactoferrin.

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2) Claims 1 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Dana (US 2003/0003059).

Dana teaches oral compositions including dental floss to treat the oral cavity (paragraph 0090). The compositions include lactoferrin (paragraph 0050), encompassing claims 1 and 13. The reference anticipates the instant claims insofar as it teaches filament compositions having a surface for reducing microbial contamination comprising lactoferrin.

Claim Rejections - 35 USC § 103 – Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 1-11 and 14-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Galley et al. (US 5,607,681) in view of Naidu (WO 00/72874).

Galley et al., the primary reference, is discussed above. The reference differs from the instant claims insofar as it does not teach lactoferrin immobilized on a biologically active substrate.

Naidu teaches compositions comprising immobilized lactoferrin to inhibit the growth of microbes on foodstuff, inanimate or non-biological surfaces, and in or on the surface of a human or non-human vertebrate (page 8, lines 5-9). Lactoferrin is unstable and loses its antimicrobial ability, thereby limiting its usefulness. Immobilizing lactoferrin helps stabilize it. Lactoferrin is bound by its N-terminus to natural substrates leaving its C-terminus free to interact with microbes. The natural substrates include proteins, polysaccharides, cellulose, nucleic acids, nucleotides, lipids, collagen, gelatin, fibronectin, casein, mucin, heparin-sulfate, carrageenan, deoxyribonucleic acid, adenosine triphosphate and triglycerides. Immobilized lactoferrin may be used in conjunction with free lactoferrin to reduce or inhibit formation of microbes. They are mixed in a ratio ranging from 0.25:1 to 1:10 immobilized lactoferrin to free lactoferrin (page 11, lines 17-24). The lactoferrin compositions may be included in pharmaceutical acceptable carriers such as cosmetics and medicaments, e.g. dental devices (page 14, lines 34-36). Carriers included polymers such as sodium alginate, carboxymethylcelluloses, hydroxypropyl cellulose and gelatin, which are hydrophilic polymers (page 13, lines 5-15). Compositions for transmucosal delivery also include a permeation enhancer, such as bile salt or fusidate and a hydrophilic polymer. These compositions are delivered on a laminated composite such as a patch (pages 16-17). The lactoferrin comprises 0.0001 mg to 10 mg/square inch of the disclosed surfaces in

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which the compositions are applied. The reference differs from the instant claims insofar as it does not teach the transmucosal delivery device or dental device is dental floss.

It would have been obvious to one of ordinary skill in the art to have used the transmucosal delivery system or other acceptable compositions comprising a mixture of immobilized lactoferrin and free lactoferrin as the lactoferrin to coat or impregnate the dental floss of the primary reference motivated by the desire to deliver the antimicrobial compositions to the tissue in between the teeth and make a dental floss that is stable in storage and when used has an enhanced rate of permeation into the tissue, as taught by the secondary reference.

In regards to claim 5, normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. In re Aller 105 USPQ 233, 235 (CCPA 1955). It would have been obvious to one of ordinary skill in the art to have adjusted the ratio of immobilized lactoferrin to free lactoferrin motivated by the desire to optimize the delivery of the lactoferrin to the targeted area, as supported by cited precedent.

2) Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fisher et al. (US 6,183,499) in view of Naidu (WO 00/72874).

Fisher et al. teaches surgical filaments comprising a multifilament core (see Abstract). The filament is coated with a biocompatible coating (col. 2, lines 50-58). The coatings may comprise medicaments such as antimicrobial agents (col. 4, lines 59-63).

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The reference differs from the instant claims insofar as it does not teach coating the surgical filaments with lactoferrin.

Naidu, the secondary reference, is discussed above. The reference differs from the instant claims insofar as it does not teach the medicament is a surgical filament.

It would have been obvious to one of ordinary skill in the art to have used the lactoferrin comprising compositions as the coatings on the surgical filament of the primary reference motivated by the desire to make a surgical filament that when used has an enhanced rate of permeation of the medicament into the tissue and to inhibit formation of microbes on the surgical filament while in storage and in use, as taught by the secondary reference.

In regards to claim 5, see above cited precedent, In re Aller 105 USPQ 233, 235 (CCPA 1955). It would have been obvious to one of ordinary skill in the art to have adjusted the ratio of immobilized lactoferrin to free lactoferrin motivated by the desire to optimize the delivery of the lactoferrin to the targeted area, as supported by cited precedent.

3) Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masterman et al. (US 5,616,315) in view of Naidu (WO 00/72874).

Masterman et al. teach oral care devices coated with an encapsulated antimicrobial agent. The devices include dental floss (see Abstract). The agents are encapsulated in polymer such as hydrophobic materials like waxes and polymethyl methacrylate (col. 4, lines 43-50) and degradable polymers such as gelatin, gum arabic

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and starch, which are hydrophilic polymers (col. 3, lines 25-40). The reference differs from the instant claims insofar as it does not teach lactoferrin as the antimicrobial agent linked to a polymer coating.

Naidu, the secondary reference, is discussed above. The reference differs from the instant claims insofar as it does not teach the medicament is a dental floss.

It would have been obvious to one of ordinary skill in the art to have used the lactoferrin comprising compositions as the coatings on the dental floss of the primary reference motivated by the desire to make a dental floss that when used has an enhanced rate of permeation of the medicament into the tissue between the teeth, to inhibit formation of microbes on the dental floss while in storage and in use and to deliver an agent that will inhibit the formation of microbes in between the teeth, as taught by the secondary reference.

In regards to claim 5, see above cited precedent, In re Aller 105 USPQ 233, 235 (CCPA 1955). It would have been obvious to one of ordinary skill in the art to have adjusted the ratio of immobilized lactoferrin to free lactoferrin motivated by the desire to optimize the delivery of the lactoferrin to the targeted area, as supported by cited precedent.

Claims 1-25 are rejected.

Claims 26-37 are withdrawn.

No claims allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lezah Roberts
Patent Examiner
Art Unit 1614



Frederick Krass
Primary Examiner
Art Unit 1614

